510(k) Summary

K091631

1.0 Date Prepared

February 8, 2010

MAR 1 8 2010

2.0 Submitter (Contact)

Martin D. Sargent
Director, Regulatory Affairs and Quality Assurance
Aspyra, Inc.
Jacksonville, FL
(904) 854-2107

3.0 Device Name

Proprietary Name:	AccessNET, AccessMED, AccessRAD, MedVIEW
Common Name(s):	Picture Archiving and Communications System, Medical Image Communications Device
Classification Name(s):	System, Image Processing, Radiological

4.0 Device Classification

Classification Name(s):	System, Image Processing, Radiological	
Procode:	LLZ Class II	21 CFR § 892.2050
	LMD Class I	21 CFR § 892.2020

5.0 Device Description

The Aspyra PACS is a system used for the management of clinical images and reports. It provides Picture Archive and Communications System (PACS) functionality as well as management of clinical workflow.

6.0 Indications for Use

The Aspyra AccessNET PACS is a software device designed to operate on specified off-the-shelf hardware and virtual environments. The device is intended to receive digital images and data from various sources including CT scanners, MR scanners, Nuclear Medicine (NM), PET, ultrasound systems, Computed & Direct radiographic devices (CR, DR), secondary capture devices, scanners, imaging gateways, etc. as well as other DICOM compliant modalities. Images and data can be captured, stored, communicated, processed, printed, and displayed within the system and or across computer networks at distributed locations.

Display and processing functions while viewing images include, but are not limited to, adjustment of window and level, rotation, zoom, measurement of anatomical structures,

image stitching, image stacking, filtration of color images (e.g. removal of red channel), annotation and measurement of regions of interest, inversion, rotation, flips, Multi-Planar Reformation (MPR), and Maximum intensity projection (MIP). In addition, users can dictate, edit, sign, and print reports.

The Aspyra AccessNET PACS is indicated for the primary review of "For Presentation" DICOM mammographic images. Lossy compressed mammographic images and digitized film screen images must not be used for primary image interpretations. Mammographic images for primary image interpretations may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

7.0 Performance testing

The results of bench testing (software verification and validation) and clinical evaluation have shown the device to be as safe and effective as the predicate devices, and raise of no new issues of safety or effectiveness. Software-related documentation consistent with moderate level of concern software as outlined in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005* has been provided in this premarket submission.

8.0 Substantial Equivalence

The Aspyra PACS is substantially equivalent in operating principle, technology, overall design, function, and intended use to ImageACCESS PACS as described in K973805. Image stitching is substantially equivalent in operating principle, technology, overall design, function, and intended use to CMT SmartRAD[K003438]and Fuji FlashIIp [K013218] [K041990], and Mammography functionality is substantially equivalent in operating principle, technology, overall design, function, and intended use to the Fuji Synapse [K051553] and GE Centricity [K082318].

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR 18 2010

Mr. Martin D. Sargent
Director, Regulatory Affairs and Quality Assurance
Aspyra, Inc.
8649 Baypine Road Ste 101
JACKSONVILLE FL 32256

Re: K091631
Trade/Device Name: AccessNET, AccessMED, AccessRAD, Medview
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 8, 2010
Received: February 16, 2010

Dear Mr. Sargent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091631
Device Name: AccessNET, AccessMED, AccessRAD, MedVIEW
Indications for Use:

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Prescription Use _X_ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ ODE

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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